1615

PATENT

Atty. Docket No.
ARC 2863 N1

J&J Ref.: AR08025US
(AR02863-US-CNT1)

CN 27777

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Suneel K. GUPTA et al.
Serial No.:	09/801,443
Filed:	March 7, 2001
For:	OXYBUTYNIN THERAPY

Group Art Unit: to be assigned

Examiner: to be assigned

INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☐ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the

mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of $180.00 as set forth in §1.17(p).

☒ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☒ Please charge Deposit Account No. 10-0750/ / the fee of $180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of $180.00 as set forth in §1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i).

☐ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☒ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750.

Respectfully submitted,

Attorney for Applicants

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SUBMISSION UNDER MPEP 609 D

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Application Number	09/801,443
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First Named Inventor	Suneel K. GUPTA
Group Art Unit	1615
Examiner Name	TRAN, Susan T.
Attorney Docket Number	ARC 2863 N1

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Name of Patentee or Applicant of Cited Document	U.S. Patent Document Number	Kind Code[2] (if known)	Pages, Columns, Lines, where relevant passages or relevant figures appear

FOREIGN PATENT DOCUMENTS

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		International Search Report dated August 8, 1999 for corresponding Appln. No. PCT/US99/06049	

Examiner Signature		Date Considered	

PTO-SB-08A (08-00)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

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	AA	2,799,241		WURSTER	07/16/1957	
	AB	3,845,770		THEEUWES et al.	11/05/1974	
	AC	3,916,899		THEEUWES et al.	11/04/1975	
	AD	4,063,064		SAUNDERS et al.	12/13/1977	
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	AS	WO	96/12477	A1	LEIRAS OY (Rantala et al.)	05/02/1996		
	AT	WO	98/43555	A1	Point Biomedical Corp.	10/08/1998		

Examiner Signature		Date Considered	

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	AU	BENZIGER, David P. et al., "Differential Effects of Food on the Bioavailability of Controlled-Release Oxycodone Tablets and Immediate-Release Oxycodone Solution", Journal of Pharmaceutical Sciences, 85(4):407-410, 1996	
	AV	CHUNG, Menger et al., "Clinical Pharmacokinetics of Nifedipine Gastrointestinal Therapeutic System", The American Journal of Medicine, 83:10-14, 1987	
	AW	GRAFTON, P., "General principles for designing with plastics", Modern Plastics Encyclopedia, 46:62-70, 1969.	
	AX	LUKKARI, Eeva, et al., Effect of time interval between food and drug ingestion on the absorption of oxybutynin from a controlled-release tablet, Pharmacol. & Toxicology, 81(1):31-34, 1997	
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	AZ	FELMEISTER, Alvin,., "Powders," Remington's Pharmaceutical Sciences, 14th Edition, Mack Publishing Co., Ch. 86, pp. 1626-1648, 1970.	
	BA	MASSAD, Charlotte A. et al., "The pharmacokinetics of intravesical and oral oxybutynin chloride", J. Urology, 148:595-597, August 1992 .	
	BB	NILSSON, Carl Gustaf et al., "Comparison of a 10-mg controlled release oxybutynin tablet with a 5-mg oxybutynin tablet in urge incontinent patients", Nerol Urodyn, 16(6):533-542, 1997.	
	BC	SATHYAN, Gayatri et al., "Effect of OROS® controlled-release delivery on the pharmacokinetics and pharmacodynamics of oxybutynin chloride", Br. J Clin. Pharmacol, 52:409-417, 2001.	
	BD	WALDECK, Kristen et al., "Comparison of oxybutynin and its active metabolite, N-desethyl-oxybutynin, in the human detrusor and parotid gland", J. Urology, 157(3):1093-1097, 1997.	
	BE	WPI / Derwent Database, "Pharmaceutical preparation prolong action urine incotinence comprise sustained release chloride pharmaceutical composition sustained release coating film non water soluble polymer ethylcellulose", Abstract of JP 05-339151, (Kodama KK), 12/21/1993	
	BF	WURSTER, Dale E., "Air-Suspension Technique of Coating Drug Particles", J. Am. Pharm. Assoc, 48(8):451-454, 1959	
	BG	WURSTER, Dale E., "Preparation of Compressed Tablet Granulations by the Air-Suspension Technique II", J. Am. Pharm. Assoc, 49(2):82-84, 1960	
	BH	YANG, Libo et al, "Modulation of Diclofenac Release From a Totally Soluble Controlled Release Drug Delivery System", Journal of Controlled Release, 44:135-140, 1997.	

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